

19. (Original) The system of claim 15 wherein the first cleat assembly is slidably passed over the first opposite end and the second cleat assembly is slidably passed over the second opposite end with the first spiked end wall directed toward the first opposite end and the second spiked end wall directed toward the second opposite end and wherein the spiked endwalls do not extend beyond the first and second opposite ends.

20. (Original) The system of claim 15 wherein one or more openings, sized to permit graft material entry into the first hollow bore, extend through the first sidewall.

21. (Currently amended) A method for inserting a vertebral implant between two vertebral endplates, wherein the vertebral implant comprises a pair of cleat assemblies and a tubular body, the method comprising:

sliding the cleat assemblies over the tubular body;  
inserting the vertebral implant between the vertebral endplates;  
interposing a distracting device between the cleat assemblies;  
applying a distracting force with the distracting device to move whereby at least one of the cleat assemblies ~~is moved~~ into engagement with at least one of the vertebral endplates.

22. (Original) The method of claim 21 further comprising:

responsive to the distractive force, expanding a space between the two vertebral endplates; and

attaching each cleat assembly to the tubular body with an attachment mechanism to maintain the expanded spacing.

23. (Original) The method of claim 22 wherein the attachment mechanism is a set screw.

24. (Original) The method of claim 21 wherein during the insertion of the vertebral implant, the cleat assemblies do not extend past the ends of the tubular body.

**REMARKS**

Claims 1-24 are pending in the application with claims 1, 12, 15, and 21 being the independent claims. Applicant requests that this paper be entered and that claims 1, 12, 15, and 21 be amended. These claim amendments should not raise new issues or require additional searching and therefore, the claims should be ready for immediate action by the Examiner. These amendments however, more particularly define the invention.

**Rejections under 35 U.S.C. § 102**

The Office Action rejected claims 1-8 and 12-24 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,702,453 to Rabbe et al.

**Claims 1, 12, and 15**

Proposed claim 1 is directed to a vertebral implant for interposition between two vertebral endplates. The implant includes:

*a tubular body sized to fit between the two vertebral endplates;*  
*a pair of ring-shaped cleat assemblies, each cleat assembly comprising an outer end wall, an inner end wall, and a side wall which defines a hollow bore,*  
*wherein one or more spikes extend from each outer end wall, and wherein each hollow bore is sized to fit over an end of the tubular body and is configured to slidably pass from the end along at least a portion of the length of the tubular body directly in an axial direction.*

The device described in the '453 patent does not disclose all the features of claim 1. For example, the device disclosed in the '453 patent is not a vertebral implant including, for example, a "hollow bore . . . configured to slidably pass from the end along at least a portion of the length of the tubular body directly in an axial direction," as recited in claim 1. Instead, the

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'453 patent discloses a vertebral body replacement having a threaded cylindrical body (21) and threaded endplates (22) (column 5, lines 52-54), that are configured to engage each other (column 6, lines 7-12; column 7, lines 41-43). Accordingly, because they are threaded, the endplates do not move directly in an axial direction.

Because the '453 patent does not disclose a vertebral implant with all the features of claim 1, claim 1 should be allowable over the '453 patent. Applicant respectfully requests that the Examiner withdraw the rejection and allow claim 1.

Proposed independent claims 12 and 15 recite, respectively, a "hollow bore . . . configured to slidably pass . . . directly in an axial direction," and "a first side wall defining a first hollow bore for slidably passing . . . directly in an axial direction." Accordingly, these claims, like claim 1, are not anticipated by the '453 patent. Applicant respectfully requests that the Examiner withdraw the rejection and allow claims 12 and 15.

Claim 21

Claim 21 is directed to a method for inserting a vertebral implant between two vertebral endplates. Applicant requests that this paper be entered amending claim 21 to further clarify the invention. The scope of claim 21, however, is unchanged, and should not raise new issues or require additional searching by the Examiner. In particular, proposed claim 21 recites:

*A method for inserting a vertebral implant between two vertebral endplates, wherein the vertebral implant comprises a pair of cleat assemblies and a tubular body, the method comprising:  
sliding the cleat assemblies over the tubular body;  
inserting the vertebral implant between the vertebral endplates;  
interposing a distracting device between the cleat assemblies;*

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*applying a distracting force with the distracting device whereby at least one of the cleat assemblies is moved into engagement with at least one of the vertebral endplates.*

The '453 patent does not disclose all of the steps recited in the method of proposed claim 21, and therefore, does not anticipate the claim. In the Response to Argument section, the Office Action identifies a rod 105 in the '453 patent as being the claimed distracting device recited in the method of claim 21. *See* Office Action, page 7. However, the device in the '453 patent, including the rod 105, does not perform the method steps as recited in claim 21.

Claim 21 recites a method including, among other things, “interposing a distracting device between the cleat assemblies; applying a distracting force with the distracting device to move at least one of the cleat assemblies into engagement with at least one of the vertebral endplates.” The '453 patent does not anticipate proposed claim 21 because the rod 105 of the '453 patent does not apply a distracting force “to move at least one of the cleat assemblies into engagement with at least one of the vertebral endplates,” as recited in claim 1. In contrast, the '453 patent discloses that the endplates engage the vertebrae using spikes (column 9, lines 64-65), a distraction plate 107 is mounted on the intact vertebrae (column 9, line 67-column 10, line 2), and the rod 105 extends through bores in the endplates 98 and are fixed to the endplates by set screws 98 (column 10, lines 4-8). The '453 patent continues, “[d]istraction of the adjacent vertebrae can be achieved by an appropriately formed instrument that can engage the collars 109 of each of the distraction plates 107” (column 10, lines 7-10).

Because the rod 105 of the '453 patent does not “apply[] a distracting force . . . to move at least one of the cleat assemblies into engagement with at least one of the vertebral endplates,” the rod cannot be the claimed distracting device. Furthermore, no other component disclosed in

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the '453 patent performs the claimed methods steps. The '453 patent discloses an “instrument that can engage the collars 109 of each of the distraction plates 107 mounted into the respective vertebrae” (column 10, lines 8-10), but neither the instrument nor the distraction plates 107 are “interpose[ed] . . . between the cleat assemblies,” as required by claim 21. Therefore, claim 21 is not anticipated by the '453 patent, and should be allowable. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection and allow claim 21.

Claims 2-8, 13, 14, 16-20, and 22-24 depend from and add additional features to independent claims 1, 12, 15, and 21. Therefore, these claims should be allowable for at least the reasons that their respective independent claim is allowable. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection and allow these claims.

Rejection Under 35 U.S.C. §103

The Office Action indicated that claims 9-11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the '453 patent. However, claims 9-11 depend from and add additional features to independent claim 1. For the reasons discussed above, claim 1 should be in condition for allowance. Therefore, claims 9-11 also should be allowable for at least those same reasons. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection and allow these claims.

Conclusion

For at least the reasons set forth above, independent claims 1, 12, 15, and 21 should be in condition for allowance. Dependent claims 2-11, 13, 14, 16-20, and 22-24 depend from and add additional features to the independent claims and, therefore, also should be in condition for allowance. Accordingly, Applicant respectfully requests that the Examiner, enter this paper,

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withdraw the outstanding rejections, and issue a formal notice of allowance.

Please grant any extension of time required to enter this response and charge any additional required fees to our Deposit Account No. 08-1394.

Respectfully submitted,



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Dated: June 5, 2006

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R137955.1

**Certificate of Service**

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Bonnie Boyle